

IN THE CLAIMS:

A version of the pending claims are presented having necessary markings to show the changes made and the current status of all pending claims in compliance with 37 C.F.R. § 1.121.

1. (CURRENTLY AMENDED) A drug delivery device comprising:
 - (i) a housing;
 - (ii) a means for generating a force capable of pushing a drug from a packaging into a human or animal body;
 - (iii) a lower barrel (30) at the end remote from the upper barrel which includes a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body[[:]], a sliding piston (48) and a means (22) for slidably receiving a packaged drug (100) configured such that a packaged drug attached thereto can slide within the device and act against said piston in the device to prime it; and
 - (iv) a means for triggering the device wherein said force generating means and said force transmitting means are configured to push the drug from the packaging into the human or animal body at a velocity of less than 20_m/s.

2. (CURRENTLY AMENDED) A drug delivery device as claimed in claim 1 wherein the housing defines:
 - (i) an upper barrel, at one end of the device which houses the force generating means; and
 - (ii) ~~a lower barrel, at the end remote from the upper barrel, which houses: a) a packaged drug; and b) the means for transmitting said force to push the drug from the packaging~~ lower barrel, said lower barrel being in operative communication with said upper barrel and said packaged drug.

3. (CANCELLED)

4. (ORIGINAL) A drug delivery device as claimed in claim 1 wherein the means for generating a force capable of pushing a drug from a packaging into a human or animal body delivers a force of from 10-40N.

5. (ORIGINAL) A drug delivery device as claimed in claim 2 wherein the means for transmitting said force to push the drug from the packaging causes the drug to be pushed from the packaging at less than 10 m/s.

6. (CANCELLED)

7. (CURRENTLY AMENDED) A drug delivery device as claimed in claim 2 wherein the packaged drug is slidably disposed in the lower barrel and comprises a packaging containing a drug, said packaging comprising a two-piece housing having a channel running there through in which is disposed a drive pin or other element, a skin piercing means and the drug; said two-piece housing further comprising i) a region allowing the packaged drug to be slidably mounted to the drug delivery device at receiving means; and ii) an end adapted to engage and tension the skin.

8. (ORIGINAL) A drug delivery device as claimed in claim 7 wherein the skin piercing means is a pioneer projectile, a syringe needle or the head of a drug splinter.

9. (ORIGINAL) A drug delivery device as claimed in claim 7 wherein the drive pin or other element has a flat or enlarged head.

10. (ORIGINAL) A drug delivery device as claimed in claim 7 further comprising a resilient means below or otherwise in association with the drive pin or other elements to ensure the drive pin is withdrawn after use.

11. (ORIGINAL) A drug delivery device as claimed in claim 1 wherein the means for generating the force capable of pushing the drug is a spring.

12. (ORIGINAL) A drug delivery device as claimed in claim 11 wherein the spring is a coil or gas spring.

13. (ORIGINAL) A drug deliver device as claimed in claim 11 wherein the force generated by the spring is adjustable.

14. (ORIGINAL) A drug delivery device as claimed in claim 13 wherein a screw cap and compression bar provide a means for adjusting the force generated by the spring.

15. (ORIGINAL) A drug deliver device as claimed in claim 11 further comprising a spring follower.

16. (ORIGINAL) A drug delivery device as claimed in claim 7 wherein the means for transmitting the force is a striker.

17. (ORIGINAL) A drug delivery device as claimed in claim 16 wherein the striker is a hammer.

18. (ORIGINAL) A drug delivery device as claimed in claim 16 wherein a region of the striker is shaped to fit a correspondingly shaped surface in a wall separating the upper and lower barrels defined by the housing such that the striker is aligned to strike the drive pin or other element in the packaged drug on actuation.

19. (ORIGINAL) A drug delivery device as claimed in claim 18 wherein the striker comprises a substantially frustoconical shoulder region which engages a substantially frustoconical surface in the wall separating the upper and lower barrels defined by the housing.

20. (ORIGINAL) A drug delivery device as claimed in claim 15 wherein the means for transmitting the force comprises a substantially conical end and the spring follower has a correspondingly shaped recess in the underside thereof.

21. (ORIGINAL) A drug delivery device as claimed in claim 16 wherein the packaged drug and striker are slidably mounted in the device such that the device can be primed by pushing the device against the skin.

22. (CURRENTLY AMENDED) A drug delivery device as claimed in claim 19 wherein the ~~device comprises a slewing spring, a sliding piston having~~ has an aperture therein and the device comprises a slewing spring and the striker, all housed in the lower barrel, ~~and the device is being~~ triggered by the sliding of the piston up the lower barrel until the shoulder region of the striker engages the shaped surface and aligns the striker with the aperture in the sliding piston such that the striker moves down the aperture under the action of the force generating means.

23. (ORIGINAL) A drug delivery device as claimed in claim 22 wherein the device is primed and actuated by a single action.

24. (ORIGINAL) A device as claimed in claim 23 wherein pushing the packaged drug up the lower barrel with sufficient force causes the device to be primed and actuated.

25. (ORIGINAL) A device as claimed in claim 23 wherein the action of pushing the packaged drug up the lower barrel with sufficient force causes the sliding piston to move up the lower barrel thereby causing the striker to be pushed up the lower barrel out of a first position in which it is not axially aligned with the aperture in the sliding piston which operatively communicates with the packaged drug and at the same time acts on a spring follower in the upper barrel causing the spring to be compressed and the device primed such that when the required delivery force is generated the striker is axially aligned with the aperture of the sliding piston and is thus actuated such that the spring acts through the spring follower and striker upon the drive pin or a like element in the packaged drug to deliver the drug into the human or animal body.

26. (ORIGINAL) A device as claimed in claim 1 wherein the device is primed and actuated by two separate actions.

27. (ORIGINAL) A drug delivery device as claimed in claim 2 wherein the upper barrel and lower barrel are formed as separate components.

28. (ORIGINAL) A drug delivery device as claimed in claim 1 wherein the drug is in a contained form.

29. (ORIGINAL) A drug delivery device as claimed in claim 28 wherein the drug is either: a liquid contained by a membrane; a liquid with a viscosity of at least 500 centipoises, more preferably at least 5000 centipoises, and more preferably still at least 100,000 centipoises; a semi solid, a paste, a gel or solid.

30. (ORIGINAL) A drug delivery device as claimed in claim 1 further comprising a packaged drug as an integral part of the device.

31. (ORIGINAL) A drug delivery device as claimed in claim 1 in which the device and/or packaged drug is sealed in a foil pouch to prevent ingress of moisture, oxygen, light, bacteria or other drug degrading or contaminating agents.

32. (ORIGINAL) A drug delivery device as claimed in claim 7 wherein the tip of the pioneer projectile or needle is positioned a few mm in from end of the packaging such that it is moving when contacting the skin.

33. (ORIGINAL) A drug delivery device as claimed in claim 7 wherein the end about the exit of the channel is in the form of a substantially annular ring located immediately about the channel exit and having a depth and width in the range 1.5 mm to 6 mm.

34. (CURRENTLY AMENDED) A drug delivery device as claimed in claim 1 further comprising a positive lock retention system to ensure the packaged drug does not come away from the device under gravity yet is free to ~~side~~ slide up the device.

35. (CURRENTLY AMENDED) A ~~single-use~~ drug delivery device as claimed in claim 59 wherein the comprising: i) a housing; ii) a pre-primed means for generating a force capable of pushing a drug from a packaging into a human or animal body; ~~iii) a means for transmitting said force to push the drug from the packaging into the human or animal body; iv) a packaged drug forming an integral part of the device; and v) a means for triggering the device wherein said force-generating means and said force-transmitting means are configured to push the drug from the packaging into the human or animal body at a velocity of less than 20 m/s~~ is pre-primed.

36. (ORIGINAL) A device as claimed in claim 35 wherein the means for triggering the device is an actuation button or like elements.

37. (CANCELLED)

38. (CURRENTLY AMENDED) A ~~packaging~~ packaged drug, for use with a drug delivery device, comprising a packaging containing a drug, said packaging comprising a housing having a channel running there through in which is disposed a drive pin or other element, a skin piercing means, and the drug, said housing further comprising i) a region allowing the packaged drug to be slidably mounted to the drug delivery device; and ii) an end adapted to engage and tension the skin.

39. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the skin piercing means is a pioneer projectile, syringe needle or the head of a drug splinter.

40. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the drug is in the form of a drug splinter.

41. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein.

42. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the packaging is substantially T-shaped.

43. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the drive pin has a flat and/or an enlarged head.

44. (ORIGINAL) A packaged drug as claimed in claim 38 further comprising a resilient means below the drive pin head to ensure the drive pin is withdrawn after use.

45. (ORIGINAL) A packaged drug as claimed in claim 38 in which the packaging comprises at two-part housing.

46. (ORIGINAL) A packaged drug as claimed in claim 38 comprising a pioneer projectile.

47. (ORIGINAL) A packaged drug as claimed in claim 38 wherein the drug is held in a contained state.

48. (ORIGINAL) A packaged drug as claimed in claim 39 wherein a hollow injection needle is disposed in the channel towards an end and a contained liquid drug is disposed in the channel there above.

49. (ORIGINAL) A packaged drug as claimed in claim 48 wherein the contained liquid drug comprises a receptacle slidably disposed in the channel and having a puncturable base, a top sealable with the drive pin or element for pushing i) the receptacle against the needle, and ii) the needle into the human or animal body thereby causing the release of the drug out of the channel and into the human or animal body when it is acted upon by the device.

50. (ORIGINAL) A packaged drug as claimed in claim 48 further comprising a resilient spacer between the needle and the receptacle.

51. (ORIGINAL) A packaged drug as claimed in claim 48 further comprising a resilient means associated with the needle such that the needle is automatically withdrawn after use.

52. (ORIGINAL) A packaged drug as claimed in claim 48 in which the needle is sharp at both of its ends.

53. (ORIGINAL) A packaged drug as claimed in claim 38 comprising a receptacle having a breakable base and being sealed by the drive pin or other element which drive pin or other element comprises an elongate body and a plurality of flexible arms.

54. (ORIGINAL) A packaged drug as claimed in claim 53 in which the arms of said element, in use, ride over one or more ramped surfaces provided on the housing such that they are displaced and/or break away from the elongate body so the elongate body of the drive pin can travel down the receptacle, causing the drug to be expelled from the base of the receptacle which breaks under the pressure exerted thereon.

55. (ORIGINAL) A packaged drug as claimed in claim 53 further comprising a pioneer projectile below the base of the receptacle.

56. (ORIGINAL) A packaged drug as claimed in claim 38 wherein a placebo is disposed behind the drug.

57. (CURRENTLY AMENDED) A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a device as claimed in claim 1 ~~or a packaged drug as claimed in claim 38.~~

58. (NEW) A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a packaged drug as claimed in claim 38 with a device as claimed in claim 1.

59. (NEW) A drug delivery device as claimed in claim 1 which is a single use drug delivery device.